DNA Banking and DNA Analysis: Points to Consider

Ad Hoc Committee on DNA Technology, American Society of Human Genetics

This publication is the only final, officially approved "DNA Banking and Analysis" statement of the American Society of Human Genetics (ASHG). Previous versions were drafts and were not intended for circulation, attribution, or citation.

These "Points to Consider" are designed to provide accurate and authoritative information in regard to the subject matter covered as of October 9, 1987. They are published with the understanding that the ASHG is not rendering medical or other professional services. The contents are intended as suggestions only. Users should rely on their own professional judgment or on consultation with other authorities and should ascertain whether more recent information has been disseminated by the ASHG or other authorities.

Preface

DNA analysis is an increasingly important source of medically useful information. Banking for the preservation of DNA needed for analysis at a future time is becoming more widespread.

DNA analysis for clinical purposes differs from many other clinical genetic tests in several ways. First, the long-term stability of DNA may permit questions to be answered later that were not envisioned at the time of its procurement. Second, since DNA analyses commonly involve linkage analysis, a concept that is unfamiliar to laypersons and to many health care professionals, there is a significant risk of misinterpretation of results by recipients. Third, the rapid advance of DNA diagnostic capabilities places special responsibilities on the providers of these services to keep current.

The following "Points to Consider" are offered primarily to help ensure that patients and families affected by genetic disease obtain and understand the information they need and desire. For this to occur, health care professionals involved in counseling, banking, or analysis must recognize their individual responsibilities.

Points to Consider

For present purposes, a "DNA diagnostic laboratory" refers to a facility that analyzes DNA to provide information about the diagnosis of a disease state or susceptibility thereto, about the diagnosis of a carrier state, or for identification purposes. A "DNA bank" is a facility that stores DNA for future analysis. One facility may serve both functions.

1. Should a DNA Diagnostic Laboratory or DNA Bank Accept Samples Directly from Patients or Only from Health Care Professionals?

A DNA diagnostic laboratory should accept samples only in response to requests from health care professionals and not in response to requests from individuals or families without the mediation of health care professionals. The health care professional should:

a. Determine what genetic information the family needs.
b. Determine whether DNA analysis is likely to provide such information.
c. Explain the possible outcomes of the proposed analyses and the significance of each.
d. Discuss the accuracy of the method.
e. Explain attendant risks, e.g., identification of nonpaternity.
f. Identify family members from whom samples may be needed.
g. Facilitate sample collection.
h. Explain the meaning and significance of any test results obtained.

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i. Explain the circumstances under which samples submitted may be reanalyzed.

The health care professional assuming the counseling role should be knowledgeable about human genetics. It is recognized that in some centers the same individual may take responsibility for both counseling and analysis.

If an individual should bank DNA without a genetic evaluation, such an evaluation is desirable before the DNA is analyzed.

2. *Who Owns the DNA in a Bank?*

Banked DNA is the property of the depositor unless otherwise stipulated. Therefore, the word "donor," which implies a gift, is inappropriate.

3. *How Can the Risk of Misunderstandings between the Depositor and the DNA Bank Be Minimized?*

The best way to avoid misunderstandings between the depositor and the DNA bank is for the bank to inform the depositor in advance in writing about the policies of the bank. It is recommended that the document presented to the depositor address the following issues:

a. The services to be provided
b. The duration of storage
c. The disposition of the DNA at the end of the agreed-upon term of storage or upon the death of the depositor
d. The conditions under which DNA can be used for purposes not requested by the depositor, e.g., research
e. A discussion of risks associated with DNA banking, such as loss of samples
f. An agreed-upon method of maintaining contact between the depositor and the bank

4. *Under What Circumstances, If Any, Should the DNA Diagnostic Laboratory Release Results to Anyone Other than the Patient?*

The results of DNA analyses should be reported to the appropriate health care professional, who in turn has the responsibility of informing the patient or family of the results and their meaning. This process should avoid needlessly informing individuals who do not wish to learn their genotype or informing one family member of another family member's genotype. The results of DNA tests, like those of other medical tests, are subject to the traditional principles of medical confidentiality and should be released to third parties only with the express consent of the individual.

5. *Under What Circumstances, If Any, Should a DNA Bank or Laboratory Transfer Deposited DNA to a Party Other than the Patient?*

The DNA laboratory must obtain express consent before transmitting patient DNA to a third party. Unless immortalized cell lines have been established, patient DNA is exhaustible and the patient's needs should take priority.

6. *What Is the Responsibility of the DNA Diagnostic Laboratory for the Accuracy of the Reported Result?*

DNA linkage results should be reported, in terms of the *probability* of a disease or carrier state, to the health care professional who submitted the samples. An error due to improper laboratory technique or due to improper estimation of disease likelihood, given the DNA results, is the responsibility of the laboratory. An error due to an incorrect statement of the genetic relationship of family members is the responsibility of the family or the health care professional submitting the samples. If a DNA sample is lost or is found to be unsuitable, the bank or laboratory has the responsibility of promptly requesting a second sample from the responsible health care professional. If the patient requests it or if the laboratory wishes to do so and has the patient's permission to do so, samples may be reanalyzed at a later time.

7. *Under What Circumstances Is It Permissible to Use Deposited DNA for Purposes Unrelated to the Original Request of the Depositor?*

This is permissible only with the express consent of the depositor. Ideally the depositor's desires should be determined at the time that the sample is collected.

8. *What Are Minimal Standards for Quality Assurance for DNA Banks?*

A DNA bank should occupy space separate from other functions, especially separate from other types of DNA work, and have secure, alarm-equipped storage facilities. The bank should maintain a manual of procedures and train personnel in meticulous technique. Samples should be coded so that a minimal number of individuals have access to the identity of the depositor. Written records should be maintained for the receipt, disposition, and storage of each sample. Each sample should be divided and stored in

more than one place. Control samples should be analyzed before deposit and at periodic intervals to demonstrate that restriction-fragment patterns are unaffected by storage. The above recommendations should not be construed as a comprehensive statement for the purposes of quality assurance.

9. *How Should the Competence of the Director of a DNA Laboratory Be Demonstrated?*

An individual directing a laboratory performing DNA analyses for clinical purposes should be required to demonstrate competence by passing an examination that requires analyzing test samples and providing appropriate risk assessments on the basis of the results.

10. *Should DNA Banks and/or DNA Diagnostic Laboratories Be Certified?*

A procedure for voluntary certification of directors of DNA banks and DNA laboratories should be established to enable directors to demonstrate competence as judged by peers.

11. *What Role Should the American Society of Human Genetics Take to Ensure That DNA Banks and Laboratories Meet Patient Needs?*

The American Society of Human Genetics should publish the above "Points to Consider" for the operation of DNA banks and DNA laboratories and make them known to relevant health professionals and governmental representatives. It should recommend establishment of a certification procedure for directors of DNA banks and DNA laboratories. It should advocate accessibility of testing for all who would benefit. It should spearhead the relevant education of other health professionals. It should address related ethical and social policy issues as they arise.

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